Great Ships Initiative

GREAT SHIPS INITIATIVE (GSI)

TECHNICAL SYSTEMS AUDIT CHECKLIST FOR SAMPLES COLLECTED DURING INTAKE

Purpose/Scope of Audit: **GSI Research, Development, Testing, and Evaluation (RDTE) Facility Technical Systems Audit**

Brief Description of Audit: Audit of sample labeling, collection, transport, and analysis at the GSI RDTE Facility during performance evaluation of the Siemens SiCURE Ballast Water Management System. Quality system documentation will be reviewed. A procedural audit will be conducted to verify that the technical aspects of this project are being performed according to GSI standard operating procedures.

Prior to interruption, see pg. 7.
↳ Fill: 9:33 am
1st sample: 9:43 am
2nd sample: 10:03 am
3rd sample: 10:23 am

Auditee: GSI scientists

Audit Location: RDTE Facility (Superior, WI)

Auditors: Kelsey R. Prihoda, GSI Assistant Quality Assurance Manager

Audit Dates: Thursday, August 27, 2009

SAMPLE BOTTLE LABELING, SAMPLE COLLECTION, AND SAMPLE TRANSPORT TO UWS

SAMPLE TEST ID: 09-SI-2 (ALSO INCLUDES IN-TANK MONITORING SAMPLE FROM 09-SI-1)

Relevant GSI SOPs:

- *GSI/SOP/G/RA/SC/3 – Procedure for Labeling Samples Collected at the GSI Land-Based RDTE Facility* in revision
- *GSI/SOP/LB/G/O/5 – Procedure for Injecting Organisms and Solids into the GSI Land-Based RDTE Facility*
- *GSI/SOP/LB/RA/SC/3 – Procedure for Algae/Small Protozoa Sample Collection*
- *GSI/SOP/LB/RA/SC/4 – Procedure for Microbial Sample Collection*
- *GSI/SOP/LB/RA/SC/6 – Procedure for Zooplankton Sample Collection*
- *GSI/SOP/LB/RA/SC/3 – Procedure for Collecting Physical/Chemical Data and Samples at the GSI Land-Based RDTE Facility* DRAFT

Sample Collection Type (Code)	Sample Port/Point	Tub Number	Sample Type (Collected By)	Labeled Correctly & In Crate?		Collected Following SOPs?		Transported Back to UWS?	
				Y	N	Y	N	Y	N
Before Fill (BF)	Pond		Phytoplankton (Euan)	✓					
			Zooplankton (Heidi Schaeffer)	✓					
Before Fill (BF)	SP2	3	Harbor Phytoplankton (Don/AMI)	✓					
			Harbor Zooplankton (Don/AMI)	✓					
Control Tub (C)	SP2	1	TRC and TRO (Heidi Schaeffer)	✓		✓			

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Sample Collection Type (Code)	Sample Port/Point	Tub Number	Sample Type (Collected By)	Labeled Correctly & In Crate?		Collected Following SOPs?		Transported Back to UWS?	
				Y	N	Y	N	Y	N
			Chem. Bucket (Don)	✓		✓			
			Phytoplankton (Euan)	✓		✓			
			Zooplankton (Don)	✓					
Pre-Treatment Tub (PT)	SP3	4	TRC and TRO (Heidi Schaeffer)	✓		✓			
			Chem. Bucket (Don)	✓		✓			
			Phytoplankton (Euan)	✓					
			Zooplankton (Don)	✓					
			Microbe Rep. 1 (Heidi Schaeffer)	✓		✓		✓ Heidi Saillard	
			Microbe Rep. 2 (Heidi Schaeffer)	✓		✓		✓	
			Microbe Rep. 3 (Heidi Schaeffer)	✓		✓		✓	
Pre-Treatment In-Line (PT)	SP3		TSS, POC, DOC Rep. 1 – 10 min. (Heidi Schaeffer)	✓		✓		✓	
			TSS, POC, DOC Rep. 2 – 30 min. (Heidi Schaeffer)	✓ + DNP		11:21 am		✓ Heidi Saillard	
			TSS, POC, DOC Rep. 3 – 50 min. (Heidi Schaeffer)	✓		11:41 am		✓ Heidi Saillard	
Filter Backwash (BW)	Line to Backwash Storage Tank		~~TRC and TRO~~ Rep. 1 – Beginning (Lana)	✓		9:45 am			✓
			~~TRC and TRO~~ Rep. 2 – Middle (Lana)	✓		11:23 am -			✓
			~~TRC and TRO~~ Rep. 3- End (Lana)	✓		See pg. 7 11:45		X	
			Disinfection Byproducts Rep. 1	✓		11:32 am		✓ Tom Mackee	
			Disinfection Byproducts Rep. 2	✓		11:32 am		✓	
Post-	SP15	6	Phytoplankton	✓					

① RE MP 8-27-09

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Sample Collection Type (Code)	Sample Port/Point	Tub Number	Sample Type (Collected By)	Labeled Correctly & In Crate?		Collected Following SOPs?		Transported Back to UWS?	
				Y	N	Y	N	Y	N
Treatment Tub (T)			Zooplankton	✓					
			Cold Water Bioassay	✓		✓		✓	
			Chem. Bucket	✓		✓		X	
			Microbe Rep. 1	✓		✓		✓ Heidi Saillard	
			Microbe Rep. 2	✓		✓		✓	
			Microbe Rep. 3	✓		✓		✓	
			Disinfection Byproducts Rep. 1	✓		✓		✓ Tom Markee	
			Disinfection Byproducts Rep. 2	✓		✓		✓	
			TRC and TRO	✓		✓			
Post-Treatment In-Line (T)	TAP		TSS, POC, DOC Rep. 1 – ~10 min. (Lana)	✓		✓ 9:42am		✓ Heidi Saillard	
			TSS, POC, DOC Rep. 2 – ~30 min. (Lana)	✓		✓ 11:21-am-pg.7		✓	
			TSS, POC, DOC Rep. 3 – ~50 min. (Lana)	✓		✓ 11:41 am		✓	
			~~? TSS, POC, DOC Rep. 3 – ~50 min. Duplicate (Lana)~~						
			* TRC and TRO Rep. 1 – ~10 min. (Lana)	✓		✓ 9:43am			
			** TRC and TRO Rep. 3/1 – ~10 min. Duplicate (Lana)	✓		✓ 11:42 am			
			** TRC and TRO Rep. 2 – ~30 min. (Lana)	✓		✓ 11:21am-pg.7			
			** TRC and TRO Rep. 3 – ~50 min. (Lana)	✓		✓ 11:40am has details			
Treatment Tank 1	Mid-Depth		TRC Monitoring – Day 1	✓		✓ 12:40pm			

*WQ DUP measured on PT Line

** TRC and TRO will be collected from Siemens PT Tap, which is inside the Siemens shipping container. This is where the Siemens staff samples from and will allow us to compare our measurements.

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SAMPLE ANALYSIS

SAMPLE TEST ID: 09-SI-2

QUALITY SYSTEM DOCUMENTATION

AUDIT QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
1. Is there an approved Quality Assurance Project Plan for the overall project and has it been reviewed by all appropriate personnel?		✓		The QAPP for this project has been reviewed by nearly all GSI staff but is not finalized + approved.
2. Is a copy of the current approved QA Project Plan maintained near laboratory work station areas?			✓	
3. Is the implementation of the project in accordance with the QA Project Plan?				
4. Are there deviations from the QA Project Plan? Explain.				
5. Do any deviations from the QA Project Plan affect data quality?				
6. Are sample handling and storage procedures in accordance with the QA Project Plan?				
7. Are written and approved current standard operating procedures (SOPs) used in the project? If so, list them and note whether they are maintained near laboratory work station areas?	✓			All SOPs used for sample collection + analysis on intake are listed in this document. There are several drafts that have not been approved, and those are indicated.
8. Are data/observations appropriately recorded in laboratory notebooks/forms according to the QA Project Plan (i.e., entries in ink, dated, initialed, corrections done properly)? Are data contained in bound, well-labeled notebooks or three-ring binders?				
9. Do supervisory and/or QA personnel inspect laboratory notebooks/forms on a regular basis and initial notebook after review?				
10. Are paper records written in indelible ink?	✓			

Additional Questions or Comments:
SOPs are in the GSI mobile laboratory with chemistry staff, and with assistant QA/QC officer (Kelsey Prichodda).

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CHEMISTRY

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/C/2 – Procedure for Determining Total Residual Oxidants (TRO) in Water*
- *GSI/SOP/BS/RA/C/3 – Procedures for Measuring Organic Carbon in Aqueous Samples*
- *GSI/SOP/BS/RA/C/6 – Procedure for Analyzing Total Residual Chlorine (TRC) Concentrations in Water*
- *GSI/SOP/BS/RA/C/8 – Procedure for Analyzing Total Suspended Solids (TSS)*

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Describe the analytical instrumentation. List the brand and model number for each instrument.	✓			See audit from 26 Aug. 09, same equipment was used.
2. Are calibration and maintenance logs kept for the instrumentation (e.g., balances and other equipment)?				
3. Review the maintenance and operational records for the equipment. Based on your findings, do all instruments/equipment appear to be in good operating condition?				
4. Are the manufacturer's operating manuals readily available to the instrumentation operators?		✓		
5. Describe the routine calibration procedure.	✓			See audit from 26 Aug. 09, same calibration procedure
6. Does the calibration documentation show that the calibration procedures are being followed?	✓			calibration is documented using data sheet.
7. Do the calibration standards have the appropriate levels (i.e., bracket the samples to be measured)?	✓			
8. What is the instrumentation calibration error according to the calibration documentation?				
9. Are duplicate samples collected and analyses conducted on at least 10% of the physical/chemical samples?	✓			1 Dup. collected from SP3 for WQ. 1 Dup. collected from PT-Tap for CH.
10. Are reagent blank samples analyzed with each set of samples?	✓			
11. Are a minimum of three and preferably more standards required for standard curves?	✓			5
12. When applicable, do routine procedures that require standard curves bracket concentrations?	✓			
13. When applicable, have analytical method detection limits been established and clearly documented?				

Additional Questions or Comments:
Iodate was used to make standard curve rather than chlorine (bleach), as better

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MICROBIOLOGY KMP reviewed datasheets 26 Oct. 2009. Data entry proofed by JJJ
Relevant GSI SOPs: 05 Oct. 2009. KMP verified 10% fill sample calculations 26 Oct. 09.

- *GSI/SOP/BS/RA/MA/1 – Procedure for Quantifying Heterotrophic Plate Counts (HPCs) using IDEXX's SimPlate® for HPC Method*
- *GSI/SOP/BS/RA/MA/3 - Procedure for the Detection and Enumeration of Enterococcus using Enterolert™*
- *GSI/SOP/BS/RA/MA/4 – Procedure for the Detection and Enumeration of Total Coliforms and E. coli using IDEXX's Colilert®*

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Are duplicate sample analyses conducted on at least 10% of the microbiology samples?	✓			6 bypss/24 analyses = 25% duplicates.
2. Are at least 10% of the samples counted by a second qualified individual (i.e., QA count)?		✓		No QA counts were conducted.
3. Are ~~reagent~~ blank samples analyzed with each set of samples? KMP 10-26-09	✓			
4. When applicable, have analytical method detection limits been established and clearly documented?	✓			

Additional Questions or Comments: Samples collected @ 12:50 and transported to UWS. None of the datasheets ("Quality control Checklist") were filled out for Trial 2 fill, ∴ time of reciept, analysis, and counts are not known.
*Samples for heterotrophic bacteria were not neutralized upon reciept in lab. Bacteria present in sample were exposed to active substance for ~48 hours. The post-treatment HPC data is not valid, and should not be used to make any decisions about biological effectiveness of the system.

PHYTOPLANKTON
Relevant GSI SOPs: Reviewed datasheets 19 October 2009. KMP.

- *GSI/SOP/LB/RA/SA/1 – Procedure for Algae/Small Protozoan Sample Analysis*

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Were all data, observations, and comments appropriately recorded on the "Ballast Water Plankton Count Sheet"?	✓ exceptions →			No initials of "sample analyzed by". Evan needs to add initials in the future.
2. Was sample assessment conducted within ~1-1.5 hours after sample collection?	✓			
3. Were at least 10% of the samples counted by a second analyst (i.e., QA count)?		✓		There is no 2nd phyto. taxonomist to do a QA sample.

*We will need to collect more phytoplankton in the future to ensure we have enough 1-day old cells to inject.

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Additional Questions or Comments:

ZOOPLANKTON

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/C/2 – Procedure for Zooplankton Sample Analysis* DRAFT

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Were all data, observations, and comments appropriately recorded on the "Zooplankton Identification Worksheet"?	✓ Tub4 - no time			And on "Documentation of Live Zooplankton" Worksheet
2. Was sample assessment conducted within ~2 hours after sample collection?	✓			Samples recieved at 13:00. Crustaceans done at ~13:45. Rotifers done
3. Were at least 10% of the samples counted by a second analyst (i.e., QA count)?		✓		We need to determine in a QA count needs to be done 1X per day if less than 10 samples were analyzed.
Additional Questions or Comments: 8 x 10^5 ~~2 6x10^5~~ Harbor Sample				

From Draft SOP: GSI/SOP/LB/RA/SA/2 - If a trial has less than 10 samples, at least 1 sample from each trial should be analyzed in duplicate ∴ from trial 2 taxonomists will need to analyze QA samples on discharge.

Additional Questions and Comments on Technical Systems Audit:

~9:47 am: Fill was interrupted due to technical issues inside the control room. Treatment and control tanks were 20% full. Chemistry samples had been collected at ~9:43 am, but tub sample was lost because valves did not close automatically. Therefore, ~20% of biology sample was lost and ~80% will be analyzed. Tubs were cleaned out and tanks began filling again at 11:00 am. The second set of chemistry/water quality samples were collected at 11:20 and the third set were collected at 11:40.

Control Sonde deployed 8/28/09 at 10:04, this is 22 hours after C2 was filled. The same happened in T2. The DO probe was not calibrated for either sonde ∴ the DO data is not accurate.

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